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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/147,052	04/05/99	SAITOH S	981167

HM12/0229

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EXAMINER	
HINES, J	
ART UNIT	**PAPER NUMBER**
1641	5

DATE MAILED: 02/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/147,052	Salt h et al.
Examiner	**Group Art Unit**
Ja-Na Hines	1641

☒ Responsive to communication(s) filed on *Apr 5, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-13* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-13* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. The use of the trademark ELISA ™ and a variety of other chemicals and diagnostic tools associated with immunodiagnostic work have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 13 is objected to under 37 CFR 1.75© as being in improper form because of an improperly dependent claim. See MEP. § 608.01(n). Claim 13 does not refer to claims 3 and 4 in the alternative form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 the phrase "..having the antigenicity of *Mycoplasma gallisepticum*..." is unclear. It is unclear whether the antigen/polypeptide has specific reactivity with *Mycoplasma gallisepticum* or if the antigen/polypeptide can cross react with *Mycoplasma gallisepticum.* Therefore the recitation of this phrase is unclear.

5. Claims 1-8 are indefinite. The specification does not teach how to make additional polypeptides derivatives. The term "derived from" is vague and indefinite, therefore it is unclear what characteristics are needed to determine whether an unknown polypeptide could be considered a derivative polypeptide. The specification neither discloses a definition for a derived polypeptide, nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine derivative polypeptides.

6. Claims 9-12 recites the limitation "a hybrid DNA" in the claims. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 9-12 are indefinite. Claims 9-12 recite DNA coding for the fusion protein, however no specific DNA sequence is recited. It is unclear what the specific amino acids as required in the DNA sequence to code for the fusion protein.

8. Claims 12 and 13 are vague. Claims 12 and 13 are drawn to a vaccine comprising a DNA coding for the fusion protein. However, the fusion protein only must contain a polypeptide having antigenicity to *Mycoplasma gallisepticum* and a polypeptide derived from a Herpes outer membrane protein. The antigenic polypeptide may not cause immunogenicity, it only must have antigenicity, i.e. cause an antibody-antigen reaction with *Mycoplasma gallisepticum* there is no specific protein size, sequence, number of requisite amino acids or fragments required by the recited polypeptide, thus there is no teaching that a peptide meeting this criteria will be effective as part of a vaccine. Further, the polypeptide derived from a Herpes outer membrane protein does not recite a specific protein size, sequence or amino acid fragment, accordingly, there is no teaching that a peptide meeting this criteria will be effective as part of a vaccine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200). Sajto et al., (WO 94/23019) teaches novel polypeptides, DNA coding for those polypeptides, recombinant vector containing the DNA, recombinant virus prepared using the vector and various uses (title). "..The polypeptide exhibits the antigenicity of *Mycoplasma gallisepticum*, a fused polypeptide comprising the above polypeptide and connected to the N-terminus thereof, a signal membrane anchor of a type II outer-membrane polypeptide of a virus that infects birds, or a polypeptide capable of reacting with a mycoplasma-immune serum or a mycoplasma-infected serum and exhibiting a substantially pure antigenicity, respectively having amino acid sequences of about 32 kDa, about 40 kDa or about 70 kDa. The expression with a recombinant virus of a polypeptide modified to such as extent as to exhibit an antigenicity equivalent to that of any of the above polypeptides. The use of a recombinant virus as a live vaccine." (Abstract). The document also teaches that the fused polypeptide can be used as an anti-*Mycoplasma gallisepticum* (MG) infectious disease vaccine and can use the recombinant fowlpox virus (FPV) which has DNA which codes for the signal membrane anchor and can be found by analyzing the hydrophobic peptide region on the N-terminus side of the type II envelop protein in reference to an amino acid sequence. However, Sajto et al., does not specifically recite a polypeptide derived from a Herpes outer membrane protein.

Yoshida et al., (Virology 1994, vol. 200) teaches the glycoprotein B genes of Marek's Disease Virus Serotypes 2 and 3 and the identification and expression by recombinant fowlpox

virus. Marek's disease is a malignant T-cell lymphoma of chickens caused by Marek's disease virus MDV), an avian herpes virus (page 484 para. 1). MDV has been classified as a gamma-herpes virus based upon its tropism, however other studies based upon its gene arrangement indicate that it is more closely related to alpha-herpes virus (page 484 para. 1). The MDV-1 homolog of the herpes simplex virus glycoproteinB (gB) has been cloned and sequenced (page 484 para .3). This gene (gB-1) encodes the B-antigen complex: gp100, gp60 and gp49 (page 484 para. 3). The gB of Herpes Simplex Virus (HSV) is the best characterized of the HSV glycoproteins and it has been shown to be essential for virus infectivity (page 484 para. 5)The gB can be one if the major target of the host immune response and in many herpes viruses, it has been reported that gB homologs are well conserved (page 484 para. 5). The recombinant fowlpox virus (FPV) have been used to express foreign genes and to evaluate their immunogenic potential (page 484 para. 6). Previous studies, show an FPV recombinant expressing the gB-1 gene to elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV (page 484-485-para, 6-1). That data suggest that FPV recombinant is a good candidate for an MDV vaccine and that gB is an important target for the host immune response (page 485 para. 1). An analysis of the predicted amino acid sequences was determined along with a 5' hydrophobic signal sequence which three of the gBps contain (page 487 para. 9). It was predicted that the N-terminal hydrophobic region of the gB-1 could serve as a signal sequence (page 488 para .1).

Therefore it would have been obvious to use the polypeptide derived from Yosida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Sajto et al., (WO 94/23019) because Sajto et al., teaches that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response.

10. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yosida et al., (Virology 1994 Vol. 200) in further view of Yangida et al. Sajto et al., (WO 94/23019) and Yosida et al., (Virology 1994 Vol. 200) have been discussed above, however neither teaches the use of a recombinant avipox virus. Yangida et al., teaches recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. The recombinant Avipoxvirus has cDNA derived from Newcastle virus inserted into a DNA region non-essential to the proliferation of Avipoxvirus. (page 2 lines 1-3). The method of constructing recombinant vaccinia virus with exogenous DNA into vaccinia virus has been devised and this method is used to obtained live vaccine (page 2 lines 4-6). Accordingly, it is possible to insert a variety of exogenous DNAs depending upon there purpose and the method is expected to used for producing live vaccines (page 2 lines 8-10). The inventors have found that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus and Newcastle Disease (page 2 lines 38-43).

Therefore it would have been obvious to use the recombinant Avipox virus with exogenous DNA as taught by Yangida et al, with the fusion polypeptide of Yosida et al., (Virology 1994 Vol. 200) and Sajto et al., (WO 94/23019) because Yangida et al., teaches that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus.

Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blacklaws et al., teaches the immunogenicity of Herpes Simplex Virus Type I glycoproteins expressed in vaccinia virus recombinants. Calvert et al., teaches fowlpox virus recombinants expressing the envelope glycoprotein of an avian virus. Kodama et al., teaches poultry mycoplasma antigens and recombinant vectors containing the genes as well as diagnostics and vaccines. Nazerian et al., teaches protection against Marek's disease by a fowlpox virus recombinant expressing the glycoprotein B of Marek's disease virus. Yoshida et al., (Virology 1994 Vol. 204) teaches the identification and characterization of a Marek's disease virus gene homologous to glycoprotein L of Herpes Simplex Virus.

Sequence Compliance

12. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the

reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. APPLICANT IS GIVEN THE TIMW WITHIN THIS APPLICATION WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

February 24, 2000

JAMES C. HOUSEL 2/28/00
SUPERVISORY PATENT EXAMINER